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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Applicant(s) : Jonathan M. Graff et al.  
Serial No. : 10/002,631  
Filing Date : October 31, 2001  
Title : METHOD TO IDENTIFY SIGNAL SEQUENCES  
Group Art Unit : 1645  
Examiner : Lambertson, D.

**SUPPLEMENTAL PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)**

**ACCELERATED EXAMINATION**

July 28, 2003

**BY HAND DELIVERY**

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Attn: 7th Floor Receptionist, TC 1600  
Examiner David Lambertson, Art Unit 1645  
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Sir:

Applicants submit herewith a detailed discussion of references supplied to the Patent Office with the Supplemental Information Disclosure Statement mailed February 3, 2003. In addition, Applicants submit a Second Supplemental Information Disclosure Statement that lists an additional relevant reference. Applicants provide a list of the relevant references and a discussion of each listed reference below.

U.S. PATENT PUBLICATION

| <u>Patent<br/>Publication<br/>No.</u> | <u>Class/<br/>subclass</u> | <u>Inventors</u>  | <u>Filing<br/>Date</u> | <u>Publication<br/>Date</u> | <u>Title</u>   |
|---------------------------------------|----------------------------|-------------------|------------------------|-----------------------------|--|
| US<br>2002/0127557<br>A1              | 435/6                      | Tan et al.        | March 9,<br>2001       | Sept. 12,<br>2002           | METHOD FOR<br>IDENTIFICATION<br>OF CDNAS<br>ENCODING SIGNAL<br>PEPTIDES  |
| US<br>2002/0076706<br>A1              | 435/6                      | Duffner<br>et al. | March<br>30, 2001      | June 20,<br>2002            | SIGNAL SEQUENCE<br>TRAPPING  |
| US<br>2002/0076706<br>A1              | 424/9.2                    | Hevezi et<br>al.  | April 30,<br>2001      | June 6,<br>2002             | NOVEL METHOD<br>OF DIAGNOSIS OF<br>PROSTATE CANCER<br>AND/OR BREAST<br>CANCER,<br>COMPOSITIONS,<br>AND METHODS OF<br>SCREENING FOR<br>PROSTATE CANCER<br>AND/OR BREAST<br>CANCER<br>MODULATORS |

US Patent Publication No. US2002/0127557A1 (Tan et al.), published September 12, 2002 and filed March 9, 2001, describes the identification and isolation of cDNAs that encode secreted and transmembrane proteins using a vector that comprises a nucleic acid fragment encoding a leaderless secretable selection protein. The vector was constructed to express fusion proteins comprising the protein encoded by the cDNA and the selection protein in a bacterial system. In particular,  $\beta$ -lactamase is used as the selectable protein to confer antibiotic

resistance to those host cells that secrete the  $\beta$ -lactamase-cDNA selection fusion protein. In the same family as US2002/0127557A1 is International Patent Application No. PCT/US02/05150, filed February 20, 2002, published September 19, 2002 as International Publication No. WO02/072821 A1.

US Patent Publication No. US2002/0076706, filed March 30, 2001, published June 20, 2002 describes methods of identifying and isolating secreted proteins or cell surface displayed polypeptides from gene libraries by using a promoter-less and secretion-less reporter gene in bacterial and eukaryotic systems. The vectors described in the application employ a cDNA library fused to the reporter gene. The source of the cDNA library may be derived from various sources, such as microorganisms, cultured mammalian cells, cells from specific tissues or organs.

US Patent Publication No. US2002/0068036 A1 (Hevesi et al.), published June 6, 2002 and filed April 30, 2001, describes methods of screening for drug candidates that modulate prostate and breast cancer by evaluating gene expression in a host eukaryotic cell of expression profile genes, such as PAA3, a prostate and/or breast cancer associated marker. The method involves contacting the host cell with a drug candidate and determining the effect of the drug candidate on the expression profile. The disclosed method allows for the identification of drug candidates that function to inhibit PAA3 activity, for example by binding to PAA3.

Hevesi et al. do not disclose or suggest a method for identifying eukaryotic signal sequences, and particularly those from mammals, in a prokaryotic system as provided by the present invention. Hevesi et al. do not teach methods for identifying and/or obtaining a candidate eukaryotic nucleic acid encoding a polypeptide which comprises a signal sequence and/or transmembrane sequence comprising:(a) contacting a bacterial cell with a plasmid

comprising a marker gene and a candidate eukaryotic nucleic acid; and (b) screening for function of the marker gene, wherein the function of the marker gene requires the presence of a signal sequence and/or a transmembrane sequence.

With regard to Duffner et al. and Tan et al., Applicants submit herewith a Declaration under C.F.R. § 1.131 setting forth facts showing the conception and reduction to practice of the invention of claims 115-144 prior to March 9, 2001, the filing date of Tan et al. and prior to March 30, 2001, the filing date of Duffner et al. In view of applicant's prior invention of the subject matter of claims 115-144, Tan et al. and Duffner et al. are not effective references against the subject matter of the present invention.

For the foregoing reasons, the subject matter of claims 115-144 is patentable over the references listed herein. Applicants request that the above-referenced application be made special in order to accelerate the examination of the application.

CONCLUSION

Applicants believe that there is no fee required with the submission of this paper. However, if such fee is due or overpayment made in connection with this submission, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 02-4377 of Baker Botts L.L.P. Duplicate copies of this page are attached.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rochelle K. Seide", written over a horizontal line.

Rochelle K. Seide  
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